

## REMARKS

Claims 15-17 are canceled. Claims 12-14 are in the application. The amendments presented above are believed to overcome the 35 U.S.C. 112, first and second paragraphs rejections. Reconsideration and withdraw are deemed proper. In order to substantiate that human LBP may be covered by the present invention, a Rule 132 Declaration will be submitted detailing experiments with human LBP, along with a new oath or declaration in compliance with 37 CFR 1.67(a).

A copy of the figures are attached in response to the Examiner's request.

The Office Action rejected claims 12 under 35 U.S.C. 102(b) as being anticipated by Gazzano-Santoro *et al.*, Infection and Immunity, 1994, Vol. 62(4): 1185-1191 ("Gazzano-Santoro"). Applicants respectfully traverse.

Applicants submit that Gazzano-Santoro does not disclose the agent of the invention. The Office Action states that "...LBP either alone or combined with [recombinant LBP<sub>23</sub>] is used as active component of an agent which anticipates claim 12." (pp. 7-8, Paper 14). Applicants respectfully disagree.

Gazzano-Santoro describes the binding affinity of recombinant bactericidal/permeability-increasing protein (rBPI) as it relates to the binding affinity of recombinant LBP (rLBP). The recombinant protein corresponding to the amino-terminal 23kDa fragment of human BPI (rBPI<sub>23</sub>) has significantly higher affinity than rLBP for lipopolysaccharide (LPS) and gram-negative bacteria. Gazzano-Santoro uses rLBP in a competitive binding assay as the 'standard' for binding affinity assays and not as an inhibitor of LPS.

The Office Action rejected claims 12, 16 and 17 under 35 U.S.C. 102(b) as being anticipated by Scott *et al.*, PCT/US94/04709 published as WO 94/25476, filed April 29, 1994 ("Scott"). Applicants respectfully traverse.

Since claims 16 and 17 have been canceled, only claim 12 needs to be addressed. Applicants submit that Scott does not disclose the present invention. The Office Action states that "Scott *et al.* teach a pharmaceutical composition compris[ing] a therapeutically effective amount of BPI variant, a LBP variant, or an LBP-BPI chimera and a pharmaceutically acceptable carrier..." (p. 8, Paper 14). Since claim 12 has been amended to exclude variant, mutants and hybrids, the Scott application no longer needs to be considered.

The Office Action rejected claims 12 and 17 under 35 U.S.C. 102(b) as being anticipated by Heavner *et al.*, PCT/US94/10760 published as WO 95/08560, filed September 24, 1993 ("Heavner"). Applicants respectfully traverse.

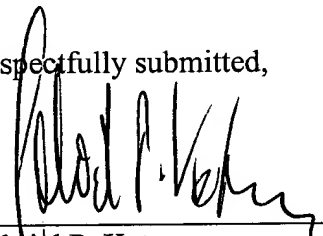
Since claim 17 has been canceled, only claim 12 needs to be addressed. Applicants submit that Heavner does not disclose the present invention. The Office Action states that "Heavner *et al.* teach pharmaceutical compositions compris[ing] peptides derived from portions of the sequences of amino acids 95-104 of LBP..." (p. 8, Paper 14). Since claim 12 has been amended to exclude variant, mutants and hybrids, the Heavner application no longer needs to be considered.

The Office Action rejected claims 12, 13, 16 and 17 under 35 U.S.C. 102(a) as being anticipated by Lamping *et al.*, Immune Consequences Trauma, Shock Sepsis, Int. Congr. 4<sup>th</sup>, March 1997, pages 15-19 ("Lamping"). Applicants respectfully traverse.

The present invention claims priority to German patent application No. 197 29 810.9, filed on July 11, 1997. An affidavit under 37 CFR 1.131 will be submitted to demonstrate prior invention.

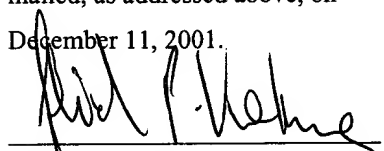
In view of the foregoing, reconsideration of the outstanding rejections, and the allowance of claims 12-15, are respectfully urged.

Respectfully submitted,

  
\_\_\_\_\_  
Gabriel P. Katona  
Attorney of Record

GOODWIN PROCTER L.L.P.  
599 Lexington Avenue  
New York, NY 10022  
Tel: (212) 813-8800  
Fax: (212) 355-3333  
Enclosures

It is hereby certified that this is being  
mailed, as addressed above, on  
December 11, 2001.

  
\_\_\_\_\_  
Gabriel P. Katona



COMPARISON COPY OF CLAIM AMENDMENTS

[--]12. An agent for the treatment of septicemia containing as the active component, [protein binding] lipopolysaccharide binding protein (LBP)[, its variants, mutants or hybrid proteins.--]

RECEIVED  
JAN 16 2002  
TECH CENTER 1600/2000

[--]13. The agent of claim 12, wherein said LBP comprises human LBP.[--]

[--]14. The agent of claim 12, wherein said LBP comprises murine LBP.[--]